REMARKS

35 U.S.C. §103

Claims **91-92** stand rejected under 35 U.S.C. §103(a) as being unpatentable over Katz *et al.* (US 5,952,392) in view of Sintov *et al.* (WO 9602244A1), further in view of Arquette *et al.* (WO 9920224). Further, claims **93-102** stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Katz *et al.* (US 5,952,392) in view of Sintov *et al.* (WO 9902244 A1), in view of Arquette *et al.* (WO 9920224), and further in view of Katz (US 4,784,794) or Katz (US 5,070,107). Applicants respectfully traverse these rejections. Applicants further submit that a *prima facie* case of obviousness has not been established.

In view of the Supreme Court decision in *KSR v. Teleflex*, and the decisions by the Board of Patent Appeals and Interferences in *Ex Parte Smith*, *Ex Parte Kubin*, and *Ex Parte Catan*, any obviousness determination must be consistent with the traditional *Graham* factors. Thus, obviousness is determined according to (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the prior art and the claimed invention, and (4) the extent of any objective indicia of non-obviousness.

Additionally, the Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. In this case, the Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Katz *et al.* reference, the Sintov *et al.* reference, the Arquette *et al.* reference, and the Katz references to arrive at the claimed invention. When asserting an obviousness rejection on these grounds, M.P.E.P. §4143 (G) requires the Examiner to "articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference to combine reference teachings;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the *Graham* inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness."

With respect to the rejections of claims **91-92** and **93-102**, the Examiner has failed to assert a *prima facie* case of obviousness. As set forth *vide supra*, even if the Examiner had put forth a *prima facie* case, it is clear that the combination of the references, taken either alone or in conjunction with the knowledge of one of ordinary skill in the art, do not, and cannot teach the claimed invention.

Claims 91-92

The Examiner proposes that Katz *et al.* (U.S. 5,952,392) "discloses that long chain fatty acids broadly including oleic acid (C18, one double bond, see col. 2 lines 12-15; col. 3, lines 5-8, col. 4, lines 26-28; col. 6, lines 28-35) or monounsaturated long chain alcohols broadly (e.g., C18-C28, or octadecenol, docosenol, brassidyl alcohol) in their effective amounts with a physiologically compatible carrier (*e.g.*, cream or ointment applied to skin, or aqueous solution, *see* col. 12, EXAMPLE 5; Examples 12, 14-15, col.20, lines 34-35, and col. 22, lines 39-40 and 64) are useful in a pharmaceutical composition for topical application, intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity *See* abstract, col. 1, lines 10-15 and 20-47; col. 3, lines 18-21; col.7, lines 62-67; col. 12, EXAMPLE 5; Examples 14-15 and col. 22-23." The Examiner further proposes that "compositions therein for use in treating viral infections comprise active ingredients [*sic*] or combination of compounds as the active ingredients selected from a group consisting of saturated aliphatic alcohols, mono-unsaturated aliphatic alcohols, mono-unsaturated aliphatic amides and aliphatic acids having a carbon chain length of 18-28 carbons, wherein the active ingredient is present in an amount of 0.1 to about 50% by weight of the final composition. *See* column 6, lines 28-36, lines 50-55. It is taught that the compositions therein are administered to the skin or a mucous membrane topically parenterally or by transmembranal penetration using a

cream, lotion, gel, ointment, suspension, aerosol spray or semi-solid formulation (*e.g.*, a suppository). *See* column 7, lines 62-67; column 24, claims 7-11."

However, Katz *et al.* (U.S. 5,952,392) does **not** disclose or teach use of "a method for treating at least one of virus-induced and inflammatory diseases [...] comprising the step of providing a topical composition consisting essentially of: at least one of octadecenol, eicosenol, docosenol, tetracosenol and hexacosenol in a concentration of from 0.1 to 25 percent by weight of an admixed physiologically active carrier; at least one salt of a jojoba-derived trans-free fatty acid according to the formula R^1-COO^-M^+, wherein: R^1 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_x$; x is at least one of 8, 10, and 12; and M^+ is a monovalent alkali metal ion; and at least one mixed ester according to the formula R^2-COO-R^3, wherein: R^2 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_y$; y is at least one of 6, 8, 10 and 12; and R^3 is at least one of an alkyl group and an aliphatic group comprising between 1 to 12 carbon atoms" as required by claim **91** of the present invention. Further, Katz *et al.* (U.S. 5,952,392) **does not teach or disclose use of *any* salts of fatty acids or mixed esters in a topical composition, let alone the salts of fatty acids and mixed esters of the instant invention *in combination with* monounsaturated long chain alcohols for treating virus-induced and inflammatory disease in accordance with the present invention**. In fact, the Examiner later admits as much by stating "[t]he prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with the particular long chain fatty acids salts such as C20 acids, and fatty acid esters herein in a composition for treating virus-induced and inflammatory disease of skin and membranes". (emphasis in original).

In regard to Arquette *et al.* (WO 9920224), the Examiner proposes that Arquette *et al.* "discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), and the instant fatty acid esters in their various percentages (see pages 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12, especially claim 23). It is also taught that fatty acids such as oleic acid, myristic acid etc are used as emollients. *See* page 1, lines 24-29." However, Arquette *et al.* does not disclose "a method for treating at least one of virus-induced and inflammatory diseases [...] comprising the step of providing a topical composition consisting essentially of: at least one

of octadecenol, eicosenol, docosenol, tetracosenol and hexacosenol in a concentration of from 0.1 to 25 percent by weight of an admixed physiologically active carrier; at least one salt of a jojoba-derived trans-free fatty acid according to the formula R^1-COO^-M^+, wherein: R^1 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_x$; x is at least one of 8, 10, and 12; and M^+ is a monovalent alkali metal ion; and at least one mixed ester according to the formula R^2-COO-R^3, wherein: R^2 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_y$; y is at least one of 6, 8, 10 and 12; and R^3 is at least one of an alkyl group and an aliphatic group comprising between 1 to 12 carbon atoms" as required by claim **91** of the present invention. In fact, Arquette *et al.* **does not teach or disclose use of *any* salts of fatty acids in a topical composition, let alone the salts of fatty acids of the instant invention *in combination with* monounsaturated long chain alcohols and mixed esters in accordance with Applicants' invention.**

Further, the Examiner proposes that "Sintov *et al.* discloses topical pharmaceutical compositions [*sic*] for the treatment of viral infections comprising salts of carboxylic acid such as alkali metal oleates, which include C18 salts. *See* abstract; page 2, bottom paragraph; page 3, lines 1-3, paragraph 5; page 7, EXAMPLE 1". However, Sintov *et al.* does not disclose "a method for treating at least one of virus-induced and inflammatory diseases [...] comprising the step of providing a topical composition consisting essentially of: at least one of octadecenol, eicosenol, docosenol, tetracosenol and hexacosenol in a concentration of from 0.1 to 25 percent by weight of an admixed physiologically active carrier; at least one salt of a jojoba-derived trans-free fatty acid according to the formula R^1-COO^-M^+, wherein: R^1 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_x$; x is at least one of 8, 10, and 12; and M^+ is a monovalent alkali metal ion; and at least one mixed ester according to the formula R^2-COO-R^3, wherein: R^2 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_y$; y is at least one of 6, 8, 10 and 12; and R^3 is at least one of an alkyl group and an aliphatic group comprising between 1 to 12 carbon atoms" as required by claim **91** of the present invention. In fact, the Sintov *et al.* reference explicitly teaches away from the use of other "any other antiviral agent" in combination with carboxylic acid salt in the treatment of viral diseases. *See* page 1, last paragraph. Sintov *et al.* **does not teach or disclose use of *any* long chain monounsaturated alcohols or mixed esters in a topical composition, let alone the monounsaturated long chain alcohols and mixed esters of the instant invention *in combination with* salts of fatty acids in accordance with the present**

invention. Moreover, the Examiner admits as much in stating "[t]he prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts, and fatty acid esters herein in a composition for treating virus-induced and inflammatory disease of skin and membranes". (emphasis in original).

Further, as cited by Applicants in their response dated 11/05/2007, the salts of fatty acids in Sintov *et al.* are different from the salts of fatty acids as presented in claim **91**. Specifically, Sintov *et al.*, page 2 last paragraph, states "the present invention provides a topical pharmaceutical composition wherein said salt is selected from the group consisting of linoleates, elaidates, palitates, myristates, oleaates, malonates, succinates, adipates, pimelates, maleates, fumarates or azelates." None of these salts comprise "a jojoba-derived trans-free fatty acid according to the formula R^1-COO^-M^+, wherein: R^1 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_x$; x is at least one of 8, 10, and 12; and M^+ is a monovalent alkali metal ion."

Moreover, Sintov *et al.* teaches away from the salts in the present invention by stating that "[e]specially preferred for use in the present invention is a water-solubilized C_{16}-C_{18} carboxylic acid salt, such as akali oleate." The salts of the present invention comprise salts of long chain fatty acids that are carbon chain lengths of 20 or greater. It is well known that salts of long-chain fatty acids are less soluble in water as compared with shorter chain fatty acids salts, and therefore it would be unexpected that salts with chain lengths greater than 18 carbons would have similar and/or improved activity relative to the more-water-soluble materials, such as those materials suggested in Sintov *et al.* *See* concurrently filed 37 C.F.R. § 1.132 Affidavit of David Ashley.

The Examiner, in failing to recognize this, asserts that

> [i]t would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the instant particular fatty acid salts such as C20 acid salts to treat viral infections in the methods of Katz et al. because Katz et al. (5,952,392) and Sintov et al teach the use of C18 acids and salts (sodium salt of oleic acid) in the method of treating viral infections....because of an expectation of success similar to that taught for structurally similar prior art species i.e. C18 acids, and salts, since structurally similar compounds usually have similar properties. See, e.g., Dillon 919, F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1559, 25 USPQ2d at 1214, and if the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species,

> In fact, similar properties may normally be presumed when compounds are very close in structure.

Applicants submit that the instant case is distinguishable from *In re Dillon* on several counts. First, the Examiner in *In re Dillon* proffered evidence of similarity between the prior art compound and the claimed compound in a composition. *Id* at 691. This reference showed that both the prior art compound and the claimed compound were structurally similar but also ***function*** similar. *Id.* ("[T]he Elliot reference shows equivalence between tetra-orthoesters [claimed compound] and tri-orthoesters [prior art compound] and that 'it is clear from the combined teachings of these references that the [claimed compound] would operate ... by the same mechanism."). In this case, the Examiner has provided no such evidence. Rather, the Examiner merely concludes that fatty acid salts in Sintov *et al.* and of the claimed invention are structurally similar, and that one would have been motivated to combine them with the other components of the claimed invention.

The Examiner has failed to appreciate Applicants' previous explanations of the narrow scope of Sintov *et al.* and that Sintov *et al.* explicitly taught away from combining salts of fatty acids with other compounds. Contrary to the Examiner's response to Applicants' assertions in regard to Sintov *et al.*, the Sintov *et al.* reference cannot be used to "broadly teach[] that salts of carboxylic acids are employed in the compositions therein for treating viral infections" when Sintov *et al.* uses the limiting language of "consisting of" repeatedly to define the salts of fatty acids. *See, e.g.*, Sintov *et al*, page 2 and claim 2.

This lack of appreciation is exemplified in the Examiner's attempted use of *In re Haas* for the proposition that "the instant particular fatty acid salts are homologs, and thus they possess the same or substantially similar activities. Absent a showing of unexpected results, homologous compounds are considered to be obvious". The Examiner's application of *In re Haas* in this case is erroneous. The court in *In re Haas* determined homologs to be "adjacent compounds" that are technically novel, but where "there is no evidence that the claimed compounds behave differently from the known compounds or have any utility or properties which would be unobvious from knowledge of the utility and properties of the claimed (known) compounds."

The Examiner makes the erroneous conclusion that salts of fatty acids of C20+ chain lengths are "homologs" of salts of fatty acids of shorter chain lengths. One of ordinary skill in the art recognizes that solubility decreases with increasing chain length, and with respect to salts of fatty acids as a delivery mechanism, the activity of shorter-chain fatty acid salts would be expected to be substantially different than that of the claimed longer-chain fatty acids salts. *See* 37 CFR §1.132 affidavit of David Ashley. Because the longer chain fatty acids of the claimed invention do not have solubility properties that map to those of shorter chain fatty acids in Sintov *et al.*, the fatty acid salts of the present invention cannot properly be viewed as homologs in accordance with *In re Haas*.

Indeed, the Examiner has not addressed the knowledge of one of ordinary skill in the art that long-chain fatty acid salts are generally less soluble than shorter-chain fatty acids, and therefore it would not have been expected that long-chain fatty acid salts would provide the proven antiviral activity of the claimed invention. Specifically, "a 100-fold increase in antiviral activity is observed where the expectation would be that the delivery mechanism would not traffic the antiviral as effectively due to the decreased solubility associated with fatty acid salts having chain lengths of 20 carbons or greater." *See* 37 CFR §1.132 affidavit of David Ashley.

Applicants respectfully request that judicial notice be taken that the Examiner has been either unwilling or unable to proffer any reference or teaching in the art that speaks to the effectiveness of ***long chain fatty acid salts alone or in combination with the fatty acid esters and long chain alcohols of the claimed invention*** *for the purpose of treating viral inventions. Instead, the Examiner asserts factually unsupported conclusions that salts of shorter-chain fatty acids (such as those in Sintov et al.) may be modified to become long chain fatty acid salts* ***and*** *combined with fatty acid esters and long chain alcohols. As such, Applicants respectfully submit that the Examiner has failed to provide a prima facie case of obviousness, and that the instant §103 rejection is improper and must be withdrawn.*

That notwithstanding, even if the Examiner had properly asserted a *prima facie* case of obviousness, Applicants have provided ample evidence of unexpected, surprising results to rebut

any such assumption. *See* application as filed, pages 23-26, and 37 C.F.R. §1.132 affidavits by David Ashley and Robert Kleiman previously submitted on 11/15/2007.

Next the Examiner proposes that "[o]ne of ordinary skill in the art at the time the invention was made would have been motivated to employ the instant long chain fatty acid salt in combination with long chain alcohols because 1) the instant long chain fatty acid salts is a homolog of alkali metal oleate, and will possess similar anti-viral properties as that of the alkali metal oleate and 2) monounsaturated long chain alcohols are known to be useful to treat virus-induced and inflammatory disease of skin and membranes according to Katz et al (5,952,392) and Sintov et al." and that there was a "reasonable expectation [sic] of success of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin and membranes."

Applicants respectfully submit that the Examiner's assertion is *non sequitur* in view of claim 91, to the extent that salts of fatty acids of the present invention cannot properly be characterized as a "homolog of alkali metal oleate"; and moreover, the combination of salts with monounsaturated alcohols and mixed fatty acid esters is not taught in the references provided by the Examiner, nor does the Examiner provide reference to knowledge generally available in the art. Furthermore, the combination of the present invention for the purpose of treatment of viral and inflammatory diseases is also not taught or suggested in the references provided by the Examiner, or in the knowledge generally available in the art.

The Examiner proposes that:

> [o]ne of ordinary skill in the art would have reasonably expected that combining the instant fatty acid esters taught by Arquette *et al.* with the monounsaturated fatty alcohols, and the salts of fatty acids [*sic*] in a pharmaceutical composition would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes because 1) fatty acid esters are known to be used as an emollient [*sic*] in pharmaceutical composition comprising monounsaturated long chain alcohols, and 2) further according to Arquette emollients have beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin. Thus, one of ordinary skill in the art would have reasonably expected that the combination of the instant fatty acid esters taught by Arquette *et al.* with the instant fatty alcohols, and the salts of oleic acid *i.e.*. instant salts of fatty acids in a pharmaceutical composition would have at least

additive therapeutic effects and also provide additional benefits such as softening, smoothening of skin."

The combination of fatty acid esters of Arquette *et al.*, fatty alcohols and salts of oleic acid to provide therapeutic effects does not teach or suggest, taken alone or in combination with the other cited references, the present invention. Specifically, "a method for treating at least one of virus-induced and inflammatory diseases [...] comprising the step of providing a topical composition consisting essentially of: at least one of octadecenol, eicosenol, docosenol, tetracosenol and hexacosenol in a concentration of from 0.1 to 25 percent by weight of an admixed physiologically active carrier; at least one salt of a jojoba-derived trans-free fatty acid according to the formula R^1-COO^-M^+, wherein: R^1 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_x$; x is at least one of 8, 10, and 12; and M^+ is a monovalent alkali metal ion; and at least one mixed ester according to the formula R^2-COO-R^3, wherein: R^2 comprises $CH_3(CH_2)_7CH=CHCH_2(CH_2)_y$; y is at least one of 6, 8, 10 and 12; and R^3 is at least one of an alkyl group and an aliphatic group comprising between 1 to 12 carbon atoms", as required by claim **91**.

Moreover, the suggested combination that the Examiner proposes does not appreciate the surprising, synergistic effects of the combination of the present invention. *See* 37 C.F.R. § 1.132 Affidavits of Robert Kleiman and David Ashley filed 11/15/2007 (discussing the 100-fold increase in antiviral activity of the present invention as compared to the antiviral activity of the alcohol alone).

In response to these affidavits, the Examiner states that "the declaration does not provide any information with respect to which unsaturated long chain alcohol, fatty acid salt, and ester are employed in the combination K100." Applicants respectfully submit that the Examiner has overlooked page 2 of the 37 CFR §1.132 affidavits of Robert Kleiman and David Ashley, which clearly state that "K100 refers to the combination of monounsaturated long chain alcohols, jojoba-derived fatty acid salts, and fatty acid esters (specifically, jojoba esters)."

Further, the Examiner is concerned that "there is no data provided for the individual fatty acid salts, and esters" and that the "declaration merely provides antiviral activity data for n-docosanol

alone, and does not provide antiviral activity data for the individual fatty acid salts and esters. Accordingly, the data is not convincing with respect to the synergistic effects of the combination of the present invention."

Moreover, pages 23-26 of the application clearly refer to the testing of "the composition of the present invention". Page 10, lines 3-page 12, line 22 of the application as filed clearly indicate that components of "the present invention" include "unsaturated wax esters", and hydrolyzed wax esters "to produce monounsaturated long chain alcohols and salts of long chain fatty acids." Applicants respectfully submit that data relating to concentrations of K100 were provided in Exhibit 1 of the 37 C.F.R. §1.132 affidavit, which is derived from pages 26-27 of the application as filed.

In summary, where the Examiner does not provide any teaching or reference for the claimed combination, nor an explanation as to how the unexpected, synergistic results of the claimed combination could be predictable, an obviousness rejection cannot be proper. Therefore, Applicants respectfully request that the rejections of claims **91-92** under §103 be withdrawn.

Claims 93-102

*Applicants hereby incorporate and reiterate all arguments/remarks made under the previous section relating to the rejection of claims **91-92** under §103 in this section.*

The Examiner asserts the following:

> "Katz *et al.* (5,952,392) does not explicitly teach the effective amount of the monounsaturated alcohol as from about 0.1 mg to about 2gm per 50 kg of body weight.
>
> Katz *et al.* (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (*e.g.*, C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3, lines 63-8, claims 1-2.
>
> Katz *et al.* (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (*e.g.*, C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular intravenous injections for methods

> of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, co.3 lines 63-68, claims 1-2.
>
> One of ordinary skill in the art would have been motivated to optimize the effective amounts of instantly claimed long chain monounsaturated alcohols in the composition because Katz *et al.* '794, and '107 teaches effective amounts of structurally similar long chain fatty alcohols active agents for treating viral infections and skin inflammations as 0.1 mg to 2 g/per 50 kg of body weight. Further, it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients in a composition in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980)."

Applicants respectfully submit that optimizing the teachings of Katz *et al.* ('392, '794, '107) references would not result in the combination of Applicants' invention. As discussed at length above, the combination of the present invention could not have been deduced from the prior art, nor was the nature of the synergistic effect of the combination of the present invention known or appreciated in the prior art. *See* 37 C.F.R. § 1.132 Affidavit of David Ashley. Specifically, data presented in the §1.132 affidavit show an at least 100-fold increase in antiviral effectiveness against the HSV-1 strain (6343). *Even if* the components of the combination of the present invention were taught separately, the resulting combination could not have been characterized as merely an optimization of parameters to obtain a "beneficial effect" in accordance with *In re Boesch*.

Applicants respectfully request judicial notice be taken that the Examiner has been either unwilling or unable to provide any combination of references or knowledge generally available in the art to teach the claimed combination and/or provide support for the Examiner's assertion that the claimed combination merely optimizes parameters to obtain a "beneficial effect" in accordance with In re Boesch.

Accordingly, the Examiner's proposition that an optimization of parameters of compositions taught in the prior art could account for the 100-fold increase in antiviral activity seen as a result of the combination of the present invention fails on two counts: (1) prior art does not teach the

composition of the present invention (*see discussion above*), and (2) the resulting effect of the combination of the present invention is more than beneficial, rather it may be more aptly characterized as synergistic and surprising (*i.e.*, substantially greater than the sum of the individual component parts). *See* concurrently filed 37 C.F.R. § 1.132 Affidavit of David Ashley.

As in the instant case, where the Examiner has not provided any teaching or reference for the claimed combination, nor any explanation as to how the unexpected, synergistic results of the claimed combination could be predicted, an obviousness rejection may not be proper applied. Therefore, Applicants respectfully request that the rejections of claims **93-102** under §103 be withdrawn.

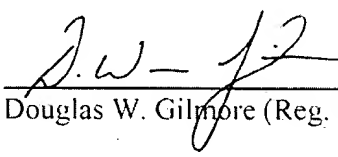
CONCLUSION

Applicants respectfully request that the Examiner provide an Advisory Action preliminary to Applicants' filing of a Notice of Appeal on or before the Shortened Statutory Deadline of 25-APR-2008.

If there are any questions or concerns, please feel free to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Date: 25-MAR-2008



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